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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,549	07/16/2003	Marianne O'Shea	059490-5016	5947

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EXAMINER	
WILLIAMS, LEONARD M	
ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/619,549	O'SHEA ET AL.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 24-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/6/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Status of Claims

The amendment/remarks received in the office 7/26/2006 amending claim 1 and 6 and adding new claims 26-27 have been entered. Claims 1-11 and 24-27 are currently pending.

The examiner acknowledges that the referral of claims 24 and 25 as the new claims was inadvertent and that applicant was correct in assuming the examiner intended to refer to claims 26 and 27 as the new claims presented.

Response to Amendment/Arguments

The applicant's have amended claim 26 to correct a misspelling. No other amendments have been made.

Applicant's arguments with respect to claims 1-11 and 24-27 have been considered but are not found persuasive.

The applicant's assert on page 5 of the remarks that Cook et al. do not disclose treating any subject with the common cold. The examiner respectfully disagrees. In the rejection detailed in the prior office action it is clearly stated that Cook et al teach a method for treating the symptoms associated with a viral infection (including members of the picornavirus such as rhinovirus-which causes more than 50% of common colds-Robbins Pathologic Basis of Disease, 5th edition, pg 322).

Cook et al. disclose the use of CLA in a method of treating symptoms associated with the production of TNF in animals (including humans) caused by viral infections. Cook et al. does specifically disclose weight loss as one symptom that can be treated but does not limit the symptoms treatable to only being weight loss. The examiner further points out that the treatment of an animal suffering a viral infection by administration of CLA would inherently treat any and all symptoms associated with infection by the virus. Thus the treatment of symptoms associated with the common cold as currently claimed are inherently treated by the method of Cook et al.

The examiner respectfully points out the following: "Products of identical chemical composition can not have mutually exclusive properties. "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The examiner respectfully points out the following from MPEP § 2112.01: "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

The applicant's have asserted on page 6 of the remarks: "However, the new use of the old composition based on the newly discovered properties can be patentable. This is the situation here." The examiner respectfully disagrees. Inherency of methods can be shown if the properties disclosed are inherent to the compositions and the methods and there is an overlapping patient population. This is clearly the case here. Cook et al. disclose the treatment of an animal suffering from a viral infection via administration of a conjugated fatty acid. Cook et al. disclose the treatment of picornavirus which includes Rhinoviruses as one of the viruses treatable with the conjugated fatty acid. There is clearly an overlapping patient population between the claimed method and the method of Cook et al. and both methods utilize the same composition for the treatments (conjugated fatty acids). Thus the method of Cook et al. clearly, and inherently, anticipates the present claimed method.

The applicant's have provided references in support of their arguments against the 102(b) rejection of the claims. The Lutwick reference is relied upon by the applicant to demonstrate that the family of picornaviruses cause an extraordinarily wide range of illnesses. Not just the common cold. The examiner respectfully notes that this does not change what Cook et al. teaches. Further on page 2 of 14, Lutwick states that picornaviruses are associated with colds and that the two major human genera of Picornaviridae are the enteroviruses and the rhinoviruses. On page 3 of 14, Lutwick teaches the rhinoviruses replicate at a pH of 6-8 and at an optimum temperature of 33°C, thus rhinoviruses primarily infect the nasal passages. Further on page 3, Lutwick states that the rhinoviruses do not spread at all from the initial site of infection. On page

6 of 14, Lutwick states that colds are one of the most infectious symptoms in humans and that approximately 70-88% of rhinovirus infections are associated with symptomatic respiratory illness.

The applicant's have provided the Dosanjh abstract to demonstrate that rhinovirus infection of the lower airways is a recognized disease. The examiner respectfully points out that this still does not change what the prior art teaches. Indeed as this is only an abstract it is not clear if this type of infection is the same as that associated with nasal infection via rhinovirus or if this is different or even something primarily associated with people susceptible to airway infections (asthmatics, smokers, impaired immune systems, etc...). As such the examiner does not see how this abstract affects the basis of the rejection.

For the reasons stated above and further for the reasons of the previous office action the 102(b) rejection is maintained over claims 1-11 and 24-27. The rejection is included below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Cook et al. (US Patent No. 5827885).

Cook et al. teach, in col. 2 lines 30-50, a method of treating symptoms associated with the production of TNF production in animals, including humans, caused by viral infection via administration of a conjugated linoleic acid (CLA).

Cook et al. teach in col. 7 lines 43-65, that the CLA utilized in the invention include cis 9, trans 11 and trans 10, cis 12 isomers. Cook et al. teach, in col. 8 lines 40-65, that the CLA compositions and their non-toxic derivatives can be added to an animal or human's food or formed into tablets, capsules, solutions, and emulsions. The exact amount to be administered depends on the CLA used but generally will be from about 1ppm to about 10,000ppm in an animal's or human's diet and that the CLA amounts to be added can range from 0.01% to 2.0% or more by weight of the animal's or human's food. As evidenced by the sample menu for a 2000 calorie food pattern from the USDA's website (mypyramid.gov/downloads/sample_menu.pdf) the total amount of food consumed daily (including proteins, carbohydrates, total fats and total dietary fiber) is 460g. If the added CLA is to be 0.01-2% then it would correspond to 0.046-9.2g daily.

Cook et al. teach, in col. 9 lines 4-20, that the method comprising administration of CLA (a conjugated fatty acid) to an animal, including a human, for the treatment of symptoms associated with viral infection includes picornavirus (which includes rhinovirus), togavirus, paramyxoviris, orthomyxovirus, rhabdovirus, reovirus, retrovirus, bunyavirus, coronavirus, arenavirus, parovirus, papovavirus, adenovirus, herpesvirus, and poxvirus anticipating the "...method of...treating a common cold...which comprises administering...conjugated fatty acids and derivatives thereof" of claim 1, the "...method...wherein said mammal is human" of claim 2, the "...method...wherein said

mammal is administered a composition comprising a conjugated fatty acid or a derivative thereof and wherein said composition is a pharmaceutical composition, a foodstuff or a food supplement" of claim 3, the "...method wherein the conjugated fatty acid or derivative thereof is conjugated linoleic acid or a derivative thereof" of claim 4, the "...method...for reducing the recovery time after a common cold" of claim 5, the "...method...wherein the common cold is caused by a coronavirus or a rhinovirus" of claim 6, the "...method...wherein the amount of conjugated fatty acid or derivative thereof is from 0.1 to about 20g of conjugated fatty acid or derivative thereof per day" of claim 7, the "...method...wherein the conjugated linoleic acid or derivative thereof comprises trans10, cis12, and cis9, trans11 isomers and the weight ratio of trans10, cis12 isomer to cis9, trans11 isomer is at least 1.2:1" of claim 8, the "...method...wherein said mammal is administered a composition comprising a conjugated fatty acid or a derivative thereof wherein said composition is a foodstuff..." of claim 9, the "...method...wherein said mammal is administered a composition comprising a conjugated fatty acid or a derivative thereof and wherein said composition is a pharmaceutical composition..." of claim 10, the "...method...wherein said mammal is administered a composition...wherein said composition is a food supplement in the form of a soft gel or hard capsule..." of claim 11, the "...method...which comprises the treatment of one or more of..." of claim 24, the "...method...for the treatment of sore throat" of claim 25, the "...method of treating a common cold..." of claim 26, and the "...method...wherein the conjugated linoleic acid...comprises trans10, cis12 and cis9, trans11 isomers..." of claim 27.

The examiner respectfully points out the following: "Products of identical chemical composition can not have mutually exclusive properties. "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The examiner respectfully points out the following from MPEP § 2112.01: "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LMW

SHENGJUN WANG
PRIMARY EXAMINER